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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/753,313

Applicant(s)

CHOI ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on March 8, 2002 in Paper No. 6 wherein claims 1-2, 4, 11, and 18-19 have been amended and claims 8-9 are cancelled. Currently, claims 1-7 and 10-21 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 10-21 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement for reasons of record stated in the Office Action dated August 24, 2001.

Applicant's remarks filed on March 8, 2002 in Paper No. 6 with respect to the rejection of claims 1-21 made under 35 U.S.C. 112, first paragraph, for scope of enablement in the previous Office Action have been fully considered but are not deemed persuasive to remove the rejection for the following reasons.

Contrary to Applicant assertion that the specification does provide reasonable enablement for "green tea, and their derivatives" or "well known derivatives of any of the foregoing substances" in the amended claims 1, 4, and 11, the specification does not clearly and precisely enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Moreover, Applicant's argument that no legal requirement to

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provide working examples in the specification is not found persuasive as discussed further below.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

In the instant case, Applicant's specification provides information that standardized green tea extract (e.g., 50% polyphenols), catechins, bioflavonoids, flavanols, flavandiols, tannins in the specification herein may be employed in the method herein. Moreover, as discussed in the previous Office Action, Applicant's specification provides examples merely showing how "standardized green tea extract" may be employed in the pharmaceutical composition useful herein to treat the claimed diseases. See Examples

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1-2 pages 29-34. Thus, the specification fails to provide sufficient working examples to support the broad use of any “derivatives” of these actives or “well known derivatives of any of the foregoing substances” in the amended claims 1, 4, and 11 in the claimed method herein.

Note that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Note that “derivatives” of these actives or “well known derivatives of any of the foregoing substances” may encompass any these actives having any possible substituents or functional groups. A skilled artisan would recognize that any significant structural variation to a compound would be reasonably expected to alter its properties. Hence, the instant claims read on all “derivatives” of these actives or “well known derivatives of any of the foregoing substances”, necessitating one of skill to perform an exhaustive search for the embodiments of “derivatives” of these actives or “well known derivatives of any of the foregoing substances” suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention absent undue experimentation.

Claim Rejections - 35 USC § 112

The following is a new rejection necessitated by Applicant's amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 10-21 are rejected under 35 U.S.C. 112, second paragraph, for the indefinite expression, " standardized green tea extract", "age-associated", and "age-related" for reasons of record stated in the Office Action dated August 24, 2001.

Claim 10 recites the limitation "plant matter" in the claim. There is insufficient antecedent basis for this limitation in the claim.

The expression " standardized green tea extract" being described as "i.e., standardized to 50% polyphenols" in the specification renders the claim indefinite since the expression "standardized green tea extract " is unclear as to the composition encompassed thereby and failing clearly set forth the metes and bounds of the patent protection desired.

The expressions "age-associated" and "age-related" brain or cognitive disorders in claim 18 render the claim indefinite since the scope of claims is indefinite as to the "age-associated" and "age-related" encompassed thereby, e.g., brain or cognitive disorders at what age would be considered as "age-associated" and "age-related". Thus, these expressions in the claims fail clearly set forth the metes and bounds of the patent protection desired.

Applicant's amendment canceling 8 filed on March 8, 2002 in Paper No. 6 with respect to the rejection of claim 8 made under 35 U.S.C. 112, second paragraph, for the indefinite expressions, e.g., "including... or", "such as", "type" and "various forms" in

claim 8 have been considered and found persuasive as to remove the particular rejection of claim 8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Castillo et al. (WO 98/51302) for reasons of record stated in the Office Action dated August 24, 2001.

Applicant's remarks filed on March 12, 2002 in Paper No. 6 with respect to this rejection of claims 1-4 and 10-11 made under 35 U.S.C. 102(b) of record stated in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicant asserts that Castillo et al. does not make any mention of green tea at all and particular mention of other active ingredients in claim 1. However, Castillo et al. clearly discloses that Uncaria tomentosa plant containing polyphenols which is known to be a primary active in green tea, is useful in methods of treatment, prevention, or management of an amyloidosis or amyloid formation, deposition, accumulation in a mammal. See page 2 lines 23-24 and 32-35 and page 3 lines 21-23 and 31-33. Thus, Castillo et al. anticipates claims 1-4 and 10-11.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10245342 for reasons of record stated in the Office Action dated August 24, 2001.

Applicant's remarks filed on March 12, 2002 in Paper No. 6 with respect to this rejection of claims 1-4 made under 35 U.S.C. 102(b) of record stated in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicant asserts that Mitsui (JP 10245342) teaches narrowly only the nerve cell toxicity caused by beta-amyloid protein by employing the same compounds, tea polyphenols. Applicant's arguments are not found persuasive since the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). As discussed in the 102(b) rejection in the previous Office Action, Mitsui's method employing the same compounds in a method of reducing the toxicity of beta-amyloid protein against nerve cells in a mammal inherently treats prevent or manage the same living animal for an amyloidosis or amyloid formation, deposition, accumulation in a mammal, as claimed herein, since Mitsui's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein.

Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps are already known even though

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applicant has proposed or claimed the mechanism. Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979).

Thus, Mitsui anticipates the claimed invention.

Claims 1-7 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Shin-Ya et al. for reasons of record stated in the Office Action dated August 24, 2001.

Applicant's remarks filed on March 12, 2002 in Paper No. 6 with respect to this rejection of claims 1-9 and 11-12 made under 35 U.S.C. 102(b) of record stated in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Contrary to Applicant assertion that Shin-Ya et al. does not make any mention by beta-amyloid protein may be reduction with catechin, Shin-Ya et al. clearly discloses that "Protective Effect of Catechin Against β -Amyloid Toxicity in Cell" (see the title of abstract). Shin-Ya et al. also clearly teaches that Alzheimer's disease is associated with accumulation of beta-amyloid protein. Applicant's arguments are not found persuasive since the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). As discussed in the 102(b)

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rejection in the previous Office Action, Shin-Ya's method employing the same compounds, e.g., catechin in a method of reducing the toxicity of beta-amyloid protein against nerve cells in a mammal inherently treats prevent or manage the same living animal for an amyloidosis or amyloid formation, deposition, accumulation in a mammal, as claimed herein, since Shin-Ya's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein. Thus, Shin-Ya et al. anticipates the claimed invention.

Claims 1-7 and 11-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultes R.E. for reasons of record stated in the Office Action dated August 24, 2001.

Applicant's remarks filed on March 12, 2002 in Paper No. 6 with respect to this rejection of claims 1-9 and 11-21 made under 35 U.S.C. 102(b) of record stated in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Again, Applicant asserts that Schultes does not make any mention whatever of green tea, *Camellia sinensis*, catechin in the amylosis treatment or fibril formation herein. Applicant's arguments are not found persuasive since the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). As discussed in the 102(b) rejection in the previous Office Action,

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Schultes' treatment employing the same compounds in a method of treating Alzheimer's disease in a mammal in a mammal inherently treats prevent or manage the same living animal for an amyloidosis or amyloid formation, deposition, accumulation in a mammal, as claimed herein, since Schultes' method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein. Thus, Schultes anticipates the claimed invention.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
May 22, 2002


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